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(71) Applicant *(for all designated States except US)*: MALLINCKRODT INC. [US/US]; 675 McDonnell Boulevard, St. Louis, MO 63134 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: RALSTON, William, H. [US/US]; 22 Rathsallagh Court, St. Charles, MO 63304 (US).

(74) Agent: GUFFEY, Wendell, Ray; Mallinckrodt Inc., 675 McDonnell Boulevard, St. Louis, MO 63134 (US).

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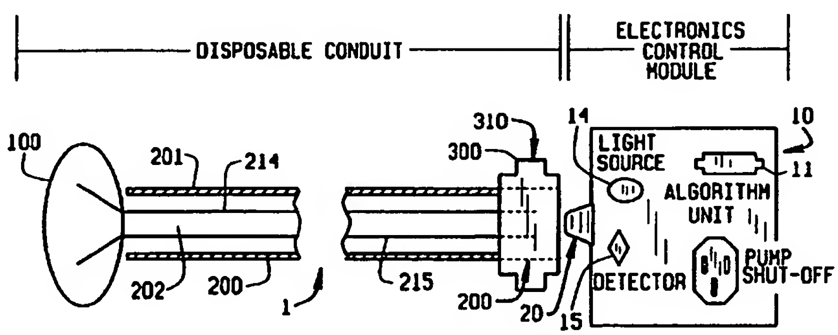

(57) Abstract

The present invention is an extravasation detection apparatus that optically detects extravasation of an injection fluid into an area of tissue during infusion. The apparatus includes an electronics control module (10), and a disposable conduit (1). The disposable conduit includes a sensor pad (100) having a lower surface for placement against a patient, and a cable (200) extending from the sensor pad to the electronics control module. At least one light source (14) is provided on either the sensor pad or the electronics control module. The light source emits light below the lower surface of the sensor pad. At least one light detector (15) is provided on either the sensor pad or the electronics control module. The detector detects the light from the light source that is reflected, scattered, diffused or otherwise emitted from the patient. The electronics control module processes signals from the detector, and evaluates whether extravasation has occurred.

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OPTICAL EXTRAVASATION DETECTION METHOD AND APPARATUS

BACKGROUND OF THE INVENTION

Field Of The Invention

The present invention relates in general to extravasation detection apparatuses. More particularly, the present invention provides an improved means that optically detects extravasation at an infusion site.

Discussion Of The Related Art

Various beneficial substances are intervascularily administered to hospital patients, , e.g., fluids such as contrast media, medicinal fluids, water, electrolytes, sugar, blood, and pharmaceuticals. These substances are typically administered with a needle that is adapted to be inserted into an appropriate vein or artery. Extravasation occurs when, during the infusion of such a substance, the substance inadvertently infiltrates the area around the vein or artery. For example, improper insertion of a needle or movement of the patient can cause the needle to pierce the vascular wall so that the substance is administered into the perivascular tissue or the needle can simply come out of the vein or artery and inadvertently inject fluid into the surrounding tissue.

Extravasation can occur while using a variety of apparatuses which inject fluids into a patient, such as, for example, syringes, power injectors, intravascular drips, intravascular pumps, etc.

A variety of injected substances can be toxic or irritating to tissue, such as substances used in diagnostic contrast enhancement or in chemotherapy, when concentrated, e.g., without dilution by blood flow. Immediate and accurate detection of extravasation can be very important with such toxic substances, as well as with other injected substances.

A variety of methods for extravasation detection are known in the art. However, there remains a need for an improved method and apparatus. Examples of known devices are illustrated in U.S. Patent Nos. 4,647,281 and 5,334,141.

The '281 patent illustrates an infiltration detection apparatus which utilizes a microwave antenna means positioned over an area of infusion and a microwave radiometer for detecting sub-cutaneous temperature. Due to temperature differentials between injected fluids and surrounding tissues, the device detects extravasation. The '141 patent illustrates another system for extravasation detection which also monitors electromagnetic microwave emission from the patient. The '141 patent shows an antenna assembly having a reusable antenna element connected to a processing apparatus and a disposable attachment element for adhering to a patient's skin.

The existing apparatuses have a number of deficiencies, and the present invention is designed to overcome the deficiencies in the existing devices and to provide an improved method and apparatus for extravasation detection.

SUMMARY OF THE INVENTION

The present invention is an apparatus and method for detecting extravasation. The invention has significant advantages over other known extravasation detection systems because it quickly and accurately detects extravasation. Further, the preferred embodiments include disposable portions that are fabricated easily and economically and allow re-use of the device.

According to a first aspect of the invention, an extravasation detection apparatus is provided which includes: at least one light source for directing light into a patient in an area proximate to a site of fluid introduction into the patient, thereby causing light to be emitted from the patient; at least one detector for detecting source light that has been reflected, scattered, diffused or otherwise emitted from the patient; and an electronics control module in communication with the detector(s) and capable of evaluating the light emitted from the patient and determining whether extravasation has occurred.

According to a second aspect of the invention, a method for detecting extravasation includes: directing light from at least one light source into a patient in an area proximate to a site of fluid introduction into the patient, thereby causing light to be emitted from the patient; detecting light reflected, scattered, diffused or otherwise emitted from the patient with at least one light detector; and evaluating the light emitted from the patient and detected by the light detector(s) with an electronics control module, so as to determine whether extravasation has occurred.

In a preferred construction, the apparatus further includes a sensor pad, a cable extending between the sensor pad and the electronics control module, the light source being located in either the sensor pad or the electronics control module, the detector being located in either the sensor pad or the electronics control module, and the electronics control module processing signals from the detector to evaluate whether extravasation has occurred.

In the preferred construction, at least one light source and at least one detector are both provided on the electronics control module.

According to another construction of the invention, the light source emits light having a wavelength between about 600 to 1800 nanometers, preferably from about 700 to 900 nanometers.

According to another preferred construction of the invention, the cable is detachable from the electronics control module. Preferably, the cable is detachable from the electronics control module via a connector, the connector being fixed to the cable and having means for removably connecting to a port of the electronics control module.

The above and other advantages, features and aspects of the present invention will be more readily perceived from the following description of the preferred embodiments

thereof taken together with the accompanying drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is illustrated by way of example and not limitation in the accompanying drawings, in which like references indicate like parts, and in which:

FIG. 1 (A) is a schematic side view of a first embodiment of the present invention;

FIG. 1 (B) is a schematic side view of a second embodiment of the present invention;

FIG. 1 (C) is a schematic side view of a third embodiment of the present invention;

FIG. 1 (D) is a schematic side view of a fourth embodiment of the present invention;

FIG. 2 is a block diagram illustrating components of the electronic control module;

FIG. 3(A) is a schematic diagram illustrating the use of the invention during the infusion of a substance into a patient via an infusion apparatus;

FIG. 3(B) is a schematic side cross-sectional view of a sensor pad against a patient according to one embodiment of the invention;

FIG. 3(C) is a schematic side cross-sectional view of a sensor pad against a patient as in FIG. 3(B) while extravasation is present; and

FIG. 4 is a graphical diagram indicating a window of opportunity for the preferred wavelengths of light used in the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is an apparatus and method for detecting extravasation. The invention operates by transmitting light into the tissue of a patient proximate to an injection site, e.g., into the tissue adjacent to a site of pharmaceutical infusion. The transmitted light enters the tissue and a portion of the light is reflected,

scattered, diffused or otherwise emitted back to the surface where it is detected by a detector. If extravasation occurs, the presence of the extravasated fluid causes the pattern of the light returning to the surface to change. The invention detects such change and determines when extravasation has occurred. The present invention can, if desired, sound an alert that extravasation has occurred or provide a signal that shuts off a device injecting fluid into the patient, e.g., a power injector.

The present invention can be used for the optical detection of extravasated fluids infused by an apparatus for intravascular infusion of fluids. Apparatuses for intravascular infusion include syringes, power injectors, intravascular drips, intravascular pumps, and a number of other known devices. The present invention can be utilized at any site of injection within the body, including both percutaneous injections and surgically exposed vasculature injections. For example, the device can be used to detect optical variations from overlying or underlying tissues or in tissues adjacent to the needle or catheter tip of an apparatus for intravascular infusion. The present invention is particularly advantageous in detecting extravasation of imaging agents and the like and can be used with other substances such as, e.g., other contrast media, medicinal fluids, electrolytes, pharmaceuticals, etc.

FIGS. 1(A)-1(D) illustrate four preferred embodiments of the present invention. Each of these embodiments includes a disposable conduit 1 and an electronic control module 10. The disposable conduit 1 preferably includes a disposable sensor pad 100, a cable 200, and connector device 300. The disposable conduit can be discarded after each use and replaced with a new disposable conduit.

The electronic control module 10 preferably includes means to interpret optically-generated signals (e.g., signals emitted from a detector), to process these signals, and to provide a warning signal and/or a pharmaceutical pump shut-off signal when extravasation occurs. A signal can also be generated to automatically interrupt any further

liquid or substance flow from the infusion apparatus. In an alternative embodiment, the electronic control module 10 can also be constructed to couple a neutralizing agent to reduce potential harm to the patient upon detection of extravasation such as in the '281 patent, the disclosure of which is incorporated herein by reference. To perform the above tasks, the electronic control module 10 can include one or more computer or microprocessor. The electronic control module 10 is preferably programmable by an operator, but the electronic control module 10 does not necessarily need to be programmable. For example, the electronic control module 10 can be programmed via a keyboard incorporated in the electronic control module 10. In addition, the electronic control module 10 can have an input for an auxiliary pre-programmed device such as an electronic strip (e.g., a read device).

A variety of known methods for evaluating variations in the pattern of reflected light can be utilized. The electronic control unit can be provided with appropriate programming for making such an evaluation. See, for example, Sevick, et al., *Frequency Domain Imaging Of Absorbers Obscured By Scattering* in J. Photochem. Photobiol. B: Biol., 16 (1992) 169-185. The foregoing article illustrates how tissue abnormalities can be detected, and even localized and characterized, by biomedical optical imaging.

As illustrated in an exemplary embodiment shown in FIGS. 3(B)-3(C), light which is emitted into the patient through the optical fiber 214 under normal conditions can have a photon migration pattern of S1, as shown in FIG. 3(B). On the other hand, when extravasation, or infiltration, occurs and the infused substance 510 enters into the field area S1, the photon migration pattern can change to another pattern because of scattering or absorption changes, e.g., S2. This change in the photon migration pattern can result in variations of the detected light received by the optical fiber 215, such that extravasation can be detected. It is contemplated that the

number of optical source fibers and of optical detection fibers can be varied, and the distribution and spacing of such fibers can also be varied depending on conditions. It is also contemplated that the light transmission can include, for example, continuous wave transmission, intermittent transmission, and modulated frequency transmission. In addition, it is also contemplated that the light detection can include, for example, scattering, absorption, and fluorescence.

The light transmitted into the patient P is preferably within a particular spectral range, or spectral window, as illustrated in FIG. 4. Most preferably, the wavelength of light transmitted is between about 700 to 900 nanometers. In this manner, the absorption factors of water, oxy-hemoglobin and deoxy-hemoglobin are minimized to facilitate detection.

As indicated, the disposable conduit 1 preferably includes three general sections: (1) a sensor pad 100; (2) a cable 200; and (3) a connector 300. FIGS. 1(A)-1(C) illustrate four preferred embodiments of the invention. FIG. 1(A) shows a most preferred construction of the invention wherein the electronic control module 10 includes a light source 14 and a light detector 15 so that light is transmitted from and received by the electronic control module 10. On the other hand, FIGS. 1(B)-1(C) illustrate that light sources and/or light detectors do not necessarily need to be part of the electronic control module 10, but can alternatively be located on the sensor pad.

More particularly, FIG. 1(A) shows an embodiment wherein at least one light source 14 and at least one light detector mechanism 15 are included as part of the electronic control module 10. Among other things, this allows the light source and detector mechanism to be retained when the disposable conduit 1 is discarded. The cable 200 and the sensor pad 100 have two or more optical source fibers 214 extending lengthwise therethrough for directing light from the light source(s) 14. The cable 200 and the sensor pad 100 also have two or more optical detector fibers 215

extending therethrough for returning reflected light back to the detector mechanism(s) 15.

In a preferred construction, the optical source fiber(s) which receive light from the light source 14 include a "fiber optic sensor" tip. There are a number of known fiber optic sensors that can be used. The fiber optic sensor can be selected based, in part, on the particular modes of light transmission and on the manner of detection utilized.

In the second embodiment illustrated in FIG. 1(B), at least one light source 14" is located on the sensor pad 100 while the light detector 15 is still located on the electronic control module 10. The light source 14" is preferably a light emitting diode ("LED") of a certain wavelength. In this second embodiment, the cable 200 includes (a) conductive wires, e.g., metallic wires, 214" for transmitting electricity to operate the at least one light source 14", e.g., to the at least one LED and (b) optical fibers 215 for collecting light as in the first embodiment shown in FIG. 1(A).

In the third embodiment illustrated in FIG. 1(C), at least one light detecting sensor 15" is located on the sensor pad 100, while the at least one light source 14 is located in the electronic control module 10. The cable 200 includes (a) optical fibers 214" for supplying light from the light source 14 and (b) conductive wires, e.g., metallic wires, 215" for transmitting electricity to operate the light detecting sensor.

In the fourth embodiment illustrated in FIG. 1(D), both the light source(s) 14" and the light detector(s) 15" are located on the sensor pad 100. Here, the cable 200 includes an appropriate number of conductive wires 214" and 215" for transmitting electricity to operate the light source(s) 14" and the light detector(s) 15", respectively.

In the preferred construction of the electronic control module 10, the module 10 includes the following components: (1) a programmed algorithm electronic unit 11 that

interprets optical input from the sensor and outputs warning and/or shut-off signals when the input parameters indicate that extravasation has occurred; (2) an audible and/or visible warning mechanism 12 and/or a shut-off mechanism 13 which receives the signals from the unit 11 -- the mechanism 13 can be, for example only, an electronic shut-off mechanism for a pharmaceutical pump (such as, e.g., for shutting-off an electrical outlet to which a pharmaceutical pump power cord is inserted); and (4) depending upon the configuration, at least one light source 14 and at least one light detector 15. In an exemplary embodiment, the light source(s) can include one or more light emitting diodes (LEDs) 16 which emit one or more wavelengths of light. In another exemplary embodiment, the light source(s) can include one or more diode lasers 17 which emit light at one or more wavelengths. The light sources can be constructed to transmit light that is, for example, a continuous wave, intermittent or frequency modulated. Although the figures schematically illustrate the electronic control module 10 as a single unit, the electronic control module 10 can include a plurality of parts or units. For example, the warning mechanism, shut-off mechanism, light sources, detectors, etc., can be separate components that are controlled by circuitry within another part of the electronic control module 10. Nevertheless, according to one preferred construction, each of the components of the electronic control module 10 are incorporated into a single unit.

The preferred construction of the sensor pad 100 includes means for emitting light from the light source and means for receiving light for the detector. These means are mounted to or embedded in the sensor pad 100 and fixed at locations and distances best suited for optimizing light propagation and detection through the thickness overlying the site of injection. The shape of the sensor pad can be varied depending on the clinical application. For example, the sensor pad can be adapted to accommodate an infusion needle 501 (see FIGS. 3(A)-3(C)). The manner of attachment of the sensor pad to the patient can also be varied

depending on the clinical application, such as with an adhesive or the like.

The cable 200 is preferably constructed with a length suitable to accommodate an appropriate infusion apparatus. For example, as shown in FIG. 3(A), the infusion apparatus 500 can be connected to a needle 501 via a connector tube adjacent to the disposable conduit 1. The cable 200 preferably includes an outer flexible sheath 201 having an interior area 202 for containing one or more source conduits (i.e., optical fibers 214 or electrical conducting wires 214") and one or more detector conduits (i.e., optical fibers 215 or electrical conducting wires 215"). In the most preferred embodiment, such as shown in FIG. 1(A), the source conduits and the detector conduits are flexible optical fibers of an appropriate diameter and length. In configurations wherein the light source and/or the detector mechanism are located within the sensor pad, such as shown in FIGS. 1(B)-1(D), the conduits within the cable 200 can be conductive wires for the transmission of an electrical current. In less preferred embodiments, the cable 200 can be a rigid structure rather than a flexible structure so that it retains a generally constant shape, or the cable can have one or more rigid sections and one or more flexible sections.

In the preferred construction of the connector 300, the connector includes an outer hub 310 surrounding the end of the cable 200 and designed to interlock with a port 20 of the electronic control module 10. The connector 300 aligns optical fibers or wires from the cable 200 with corresponding means in the electronic control module to optically or electrically communicate with the electronic control module 10. The mechanism by which the connector 300 interlocks with the port 20 can include, as some examples, (1) a Luer-Lock® connection (e.g., a Luer fitting), (2) a threaded connection (e.g., having either male or female threads depending upon the electronic control module); (3) a snap-fit connection, such as with alignment grooves or with one or more raised alignment ridges; as well as (4) any

other known type of co-axial connection. Alternatively, the connector can include an intermediate cable segment which communicates with both the cable 200 and the electronic control module 10.

The present optical extravasation detection system has significant advantages over other known extravasation detection systems. The present invention enables accurate and immediate detection of extravasation, allowing for an immediate response to such detection. The disposable conduit of the preferred embodiments can also be relatively easily and economically fabricated, facilitating re-use of the device by attaching a new disposable conduit.

While the present invention has been shown and described with reference to preferred embodiments presently contemplated as best modes for carrying out the invention, it is understood that various changes may be made in adapting the invention to different embodiments without departing from the broader inventive concepts disclosed herein and comprehended by the claims which follow.

CLAIMS

What is claimed is:

1. An extravasation detection apparatus comprising:

at least one light source for directing light into a patient in an area proximate to a site of fluid introduction into said patient;

at least one detector for detecting source light that is reflected, scattered, diffused or otherwise emitted from said patient; and

an electronics control module in communication with said detector(s) and capable of evaluating said light emitted from said patient and determining whether extravasation has occurred.

2. The apparatus of claim 1, further including a sensor pad, a cable extending between said sensor pad and said electronics control module, said light source being located in either said sensor pad or said electronics control module, said detector being located in either said sensor pad or said electronics control module, and said electronics control module processing signals from said detector to evaluate whether extravasation has occurred.

3. The apparatus of claim 2, wherein said light source is provided in said electronics control module.

4. The apparatus of claim 3, wherein said detector is provided on said electronics control module.

5. The apparatus of claim 2, wherein said at detector is provided in said electronics control module.

6. The apparatus of claim 2, wherein said light source is provided in said sensor pad.

7. The apparatus of claim 6, wherein said detector is provided in said sensor pad.

8. The apparatus of claim 2, wherein said detector is provided in said sensor pad.

9. The apparatus of claim 1, wherein said light source emits light having a wavelength between about 600 to 1800 nanometers.

10. The apparatus of claim 2, wherein said cable is detachable from said electronic control module.

11. The apparatus of claim 2, wherein said cable is detachable from said electronic control module via a connector, said connector being fixed to said cable and having means for removably connecting to a port of said electronic control module.

12. The apparatus of claim 1, wherein said light source is a light emitting diode.

13. The apparatus of claim 1, wherein said light source is a diode laser.

14. The apparatus of claim 3, wherein said cable includes at least one optical fiber extending through said cable for directing light from said light source to be emitted from of said sensor pad.

15. The apparatus of claim 4, wherein said cable includes at least one optical fiber extending through said cable for receiving light from said sensor pad and directing light to said detector.

16. The apparatus of claim 6, wherein said cable includes at least one conductive wire extending through said cable for operating said light source in said sensor pad.

17. The apparatus of claim 7, wherein said cable includes at least one conductive wire extending through said cable for operating said detector in said sensor pad.

18. The apparatus of claim 1, wherein said electronics control module sends a signal to a warning mechanism when extravasation occurs.

19. The apparatus of claim 1, wherein said electronics control module sends a signal to a shut-off mechanism when extravasation occurs.

20. A method of determining if extravasation has occurred in a patient comprising the steps of:

directing light from at least one light source into a patient in an area proximate to a site of fluid introduction into said patient;

detecting source light that is reflected, scattered, diffused or otherwise emitted from said patient with at least one light detector; and

evaluating the light emitted from said patient and detected by said light detector(s) with an electronics control module, so as to determine whether extravasation has occurred.

21. The method of claim 20, further including the steps of providing a sensor pad, providing a cable extending between said sensor pad and said electronics control module, locating said light source in either said sensor pad or said electronics control module, locating said detector in either said sensor pad or said electronics control module, and having said electronics control module process signals from said detector to evaluate whether extravasation has occurred.

22. The method of claim 21, further including the step of providing said light source in said electronics control module.

23. The method of claim 22, further including the step of providing said detector in said electronics control module.

24. The method of claim 21, further including the step of providing said detector in said electronics control module.

25. The method of claim 21, further including the step of providing said light source in said sensor pad.

26. The method of claim 25, further including the step of providing said detector in said sensor pad.

27. The method of claim 21, further including the step of providing said detector in said sensor pad.

28. The method of claim 20, further comprising the step of emitting light having a wavelength between about 600 to 1800 nanometers from said light source.

29. The method of claim 21, further comprising the step of detachably connecting said cable to said electronic control module.

30. The method of claim 20, further comprising the step of providing said light source with a light emitting diode.

31. The method of claim 20, further comprising the step of providing said light source with a diode laser.

32. The method of claim 22, further including the steps of providing at least one optical fiber extending through said cable for directing light from said light source to be emitted through said sensor pad.

33. The method of claim 23, further including the steps of providing said cable with at least one optical fiber extending through said cable for receiving light through said sensor pad and directing said light to said detector.

34. The method of claim 25, further including the steps of providing said cable with at least one conductive wire extending through said cable for operating said light source in said sensor pad.

35. The method of claim 26, further including providing the cable with at least one conductive wire extending through said cable for operating said detector in said sensor pad.

36. The method of claim 20, further including the step of sending a signal from said electronic control module to a warning mechanism when extravasation occurs.

37. The method of claim 20, further including the step of sending a signal from said electronics control module to a shut-off mechanism when extravasation occurs.

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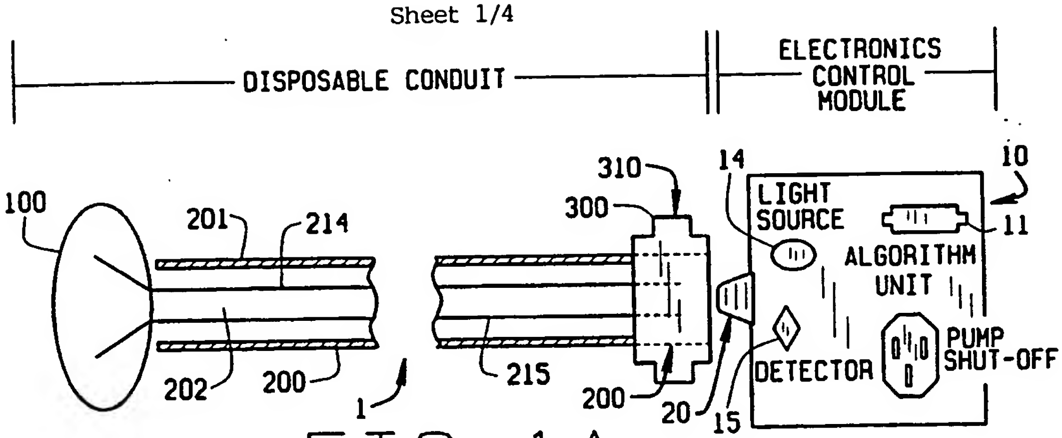

FIG. 1A

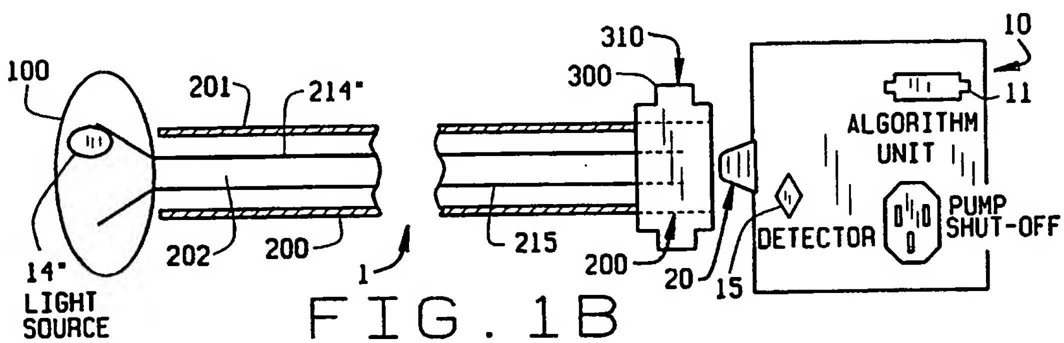

FIG. 1B

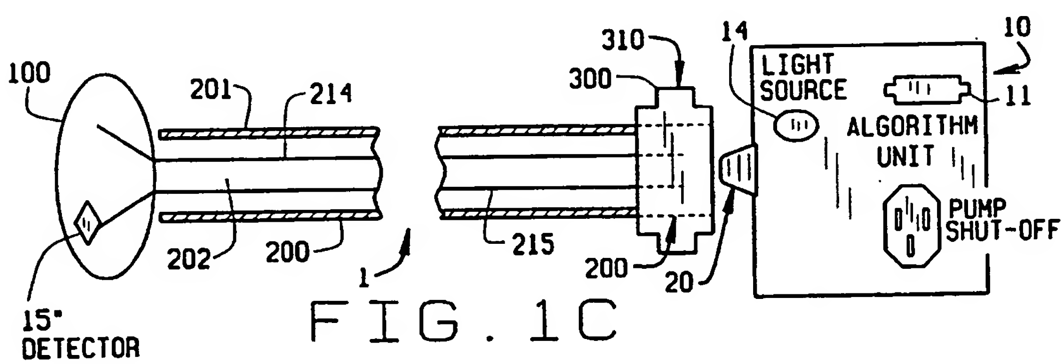

FIG. 1C

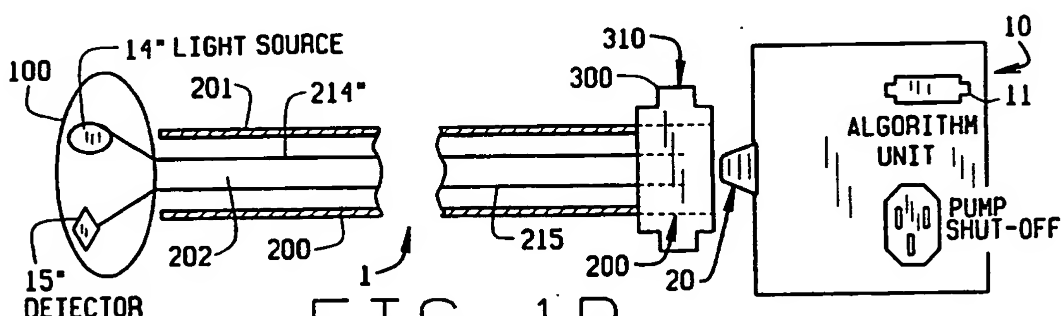

FIG. 1D

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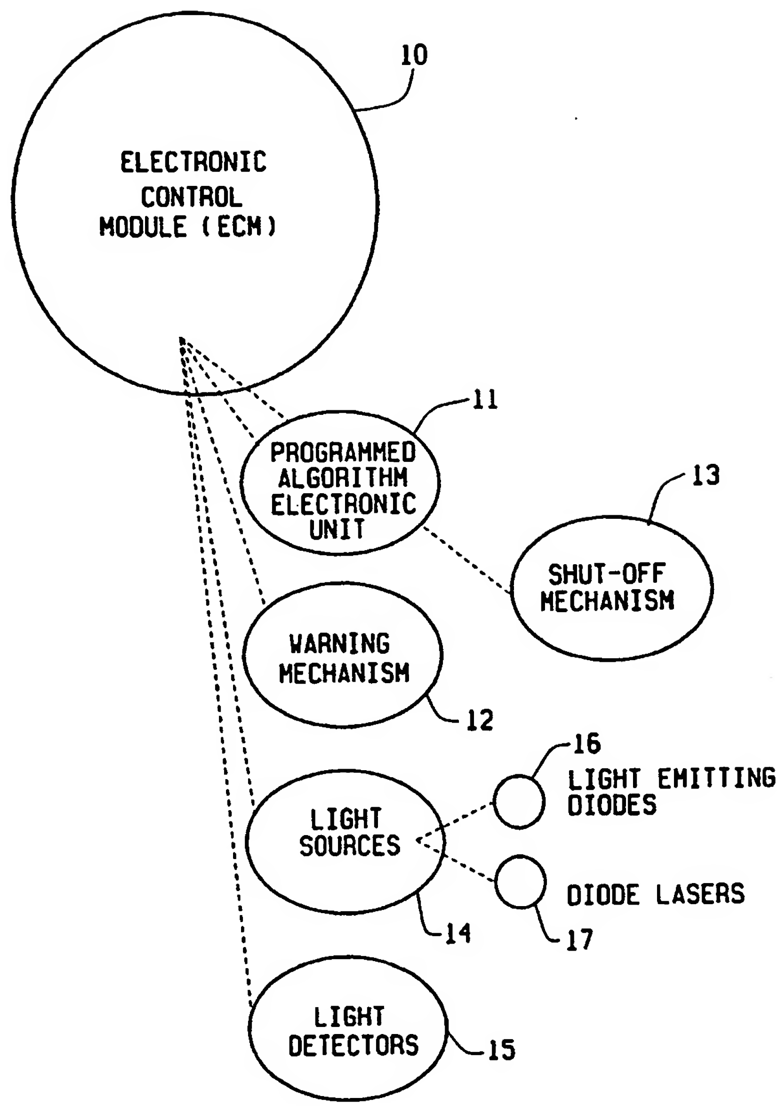

FIG. 2

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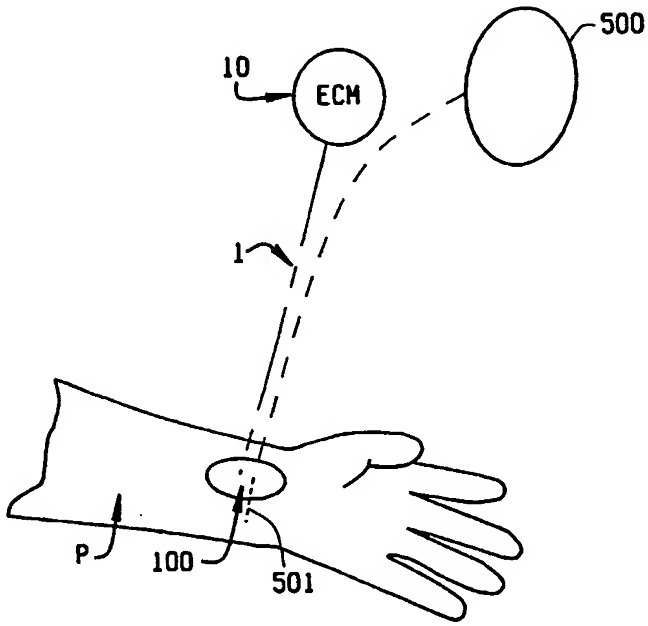

FIG. 3A

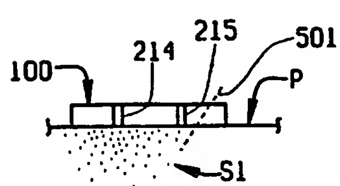

FIG. 3B

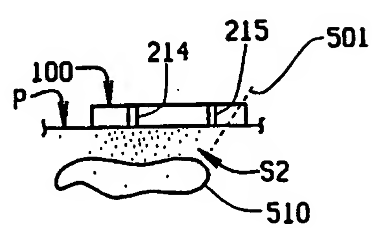

FIG. 3C

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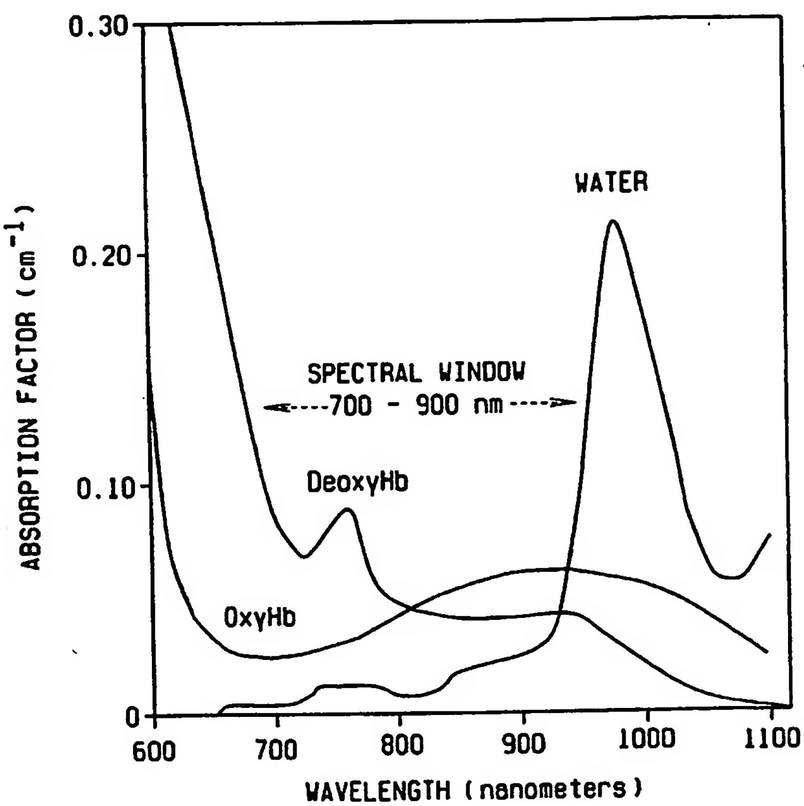

FIG. 4